

REMARKS

Applicants appreciate the thorough examination of the present application as evidenced by the Office Action dated October 13, 2006 (hereinafter, "Office Action").

Upon entry of the present Amendment, Claims 1, 3, 6-19 and 23-32 are pending in the present application. Applicants respectfully submit that Claims 1, 3, 6-19 and 23-32 are patentable for at least the foregoing reasons.

I. Claim Objections

Claims 23 and 28 stand objected to on the basis that these claims depend from rejected Claim 1. Office Action, page 2. Applicants have added Claims 29 and 30, which represent Claims 23 and 28, respectively, written in independent format. For reasons discussed below, Claim 23 is patentable over the cited references and Claim 28 is not subject to any rejections in the Office Action. Accordingly, Claims 23 and 28 and new independent Claims 29 and 30 are believed to be patentable.

II. Claim Rejections Under 35 U.S.C. §112, First Paragraph, Written Description

The rejection of Claims 1, 17, 18, 26 and 27 under 35 U.S.C. §112, first paragraph, as lacking written description is maintained for reasons of record. *See* Office Action, page 2. More specifically, the Office Action of July 5, 2006 states that, among other things, "[t]here is no identification of any particular amounts or proportions of the kieselguhr and perlite particles in the mixtures. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus." July Office Action, page 8. Applicants respectfully disagree.

Claim 1 recites "kieselguhr or perlite particles or mixtures thereof." Accordingly, the claimed filter can include (a) 100% kieselguhr, (b) 100% perlite or (c) any mixture of kieselguhr and perlite in any percentage or proportion to provide a mixture of the two components. The July Office Action asserts that the skilled artisan cannot envision any particular amounts or proportions. However, the skilled artisan is indeed capable of doing just that where the particular amounts are 100% kieselguhr, 100% perlite or any mixture of kieselguhr and perlite.

Concerning the allegation that there is an absence of sufficient recitations of distinguishing identifying characteristics, such characteristics relate to the kieselguhr and perlite compounds themselves. In interpreting the written description requirement, the USPTO has clearly stated that "[i]nformation which is well known in the art need not be described in detail in the specification." *Guidelines for Examination of Patent Applications Under the 35 USC 112 ¶1, "Written Description" Requirement*, Federal Register 66, p. 1105 col. 3 (Jan. 5, 2001) (hereinafter, "Written Description guidelines")(relying on *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d at 1367, 1379-80, 231 USPQ 81, 90 (Fed. Cir. 1986)). Applicants respectfully submit that no further description is necessary where these chemical compounds and characteristics are well-known in the art. Moreover filters including these compounds are commercially available. *See attached* product data sheets.

Furthermore, the skilled artisan would select kieselguhr, perlite or any mixture of kieselguhr and perlite dependent upon the material being filtered. As known by those skilled in the art, kieselguhr is generally characterized as a coarser material, while perlite is generally characterized as a finer material. In fact, upon review of cited reference GB 2 045 828 A to Ostreicher et al. (hereinafter, "Ostreicher et al."), it is clear that the skilled artisan would have no difficulty in producing a depth filter having a given proportion of kieselguhr and perlite. For example, Ostreicher et al. discusses the use of mixtures of diatomaceous earth (i.e., kieselguhr) and perlite on page 3, lines 29-41. This reference reinforces that the skilled artisan could readily make a depth filter including kieselguhr, perlite or any mixture thereof.

Accordingly, the skilled artisan, without undue experimentation, could select the proportions of kieselguhr and perlite based upon the material to be filtered, and as provided in the pending claims, so long as the depth filter has a pore size providing a retention less than 6 μm , an objective of the present invention can be achieved.

At least in view of the foregoing, Applicants respectfully submit that the pending claims comply with the written description requirement, and Applicants respectfully request that this rejection be withdrawn.

III. Claim Rejections Under 35 U.S.C. § 103

Applicants appreciate the indication that the rejection of Claims 1, 7-19 and 25-27 under 35 U.S.C. §103(a) as being unpatentable over WO 96/05846 to Nebe (hereinafter,

"Nebe"), U.S. Patent No. 5,696,236 to Omar et al. (hereinafter, "Omar et al.") and EP 0798003A2 to Savage et al. (hereinafter, "Savage et al.") have been withdrawn.

However, Claims 1, 3, 6-19, 23 25-27 and 29 stand rejected as being obvious in view of newly cited reference Ostreicher et al. in view of Nebe as evidenced by Encyclopedia Britannica (britannica.com/eb/article-9030299/diatomaceous-earth, access 10/5/2006). *See* Office Action, page 3. More specifically, the Office Action states that "[o]ne of ordinary skill in the art would have had a reasonable expectation of success to use Ostreicher's filter to remove Nebe's prion proteins because Ostreicher's filter is capable of removing submicron contaminants." Office Action, page 5. Applicants respectfully disagree with this assertion.

At the time of the present invention, there was very limited knowledge of the properties of **abnormal** prion proteins, which differ from **normal** prion proteins by possessing an altered three-dimensional tertiary structure. Submitted herewith is a Declaration of Ian MacGregor, Ph.D. Pursuant to 37 C.F.R. §1.132 (hereinafter, "the MacGregor Declaration").¹ The MacGregor declaration compares the difference in properties of normal and abnormal prion proteins derived from their three-dimensional structure. In particular, the particle size of prion proteins was not characterized. As set forth in paragraph 5 of the MacGregor declaration, normal prior proteins exist in nature mainly as a monomer, whereas infectious prion proteins are often found in fibrils of much larger particle size. However, at the time of the present invention, it was not known whether filtration would be an effective method of removing abnormal prion proteins, and it was certainly not known what pore size would be appropriate, in view of the poorly characterized properties of abnormal prion proteins. Thus, the effective particle size of the abnormal prion protein was not well understood. Moreover, electrical attractions between the abnormal prion proteins and the filter materials, which account for the absorption properties of depth filters, were also unknown. Therefore, while the Office Action asserts that it was known that prion proteins were submicron contaminants and that Nebe removed submicron contaminants (*see* Office Action citation above), this conclusion ignores the fact that abnormal prion proteins were largely unknown and not characterized as "submicron contaminants" at the time of the present application. One of ordinary skill in the art would not have known (a) whether prion proteins could be effectively removed by filtration, (b) the appropriate type of filter, and/or

¹ Previously submitted to the U.S. Patent and Trademark Office in co-pending U.S. Patent Application Serial No. 10/512,471 (Attorney Docket No. 9052-67).

(b) the filter pore size. Further, Applicants have amended Claim 1 to include the transitional phrase "consisting essentially of" to clarify that the claims are directed to the use of only one type of filter. Thus, Applicants respectfully submit that the pending claims are not obvious in view of the cited references.

IV. New Claim 32

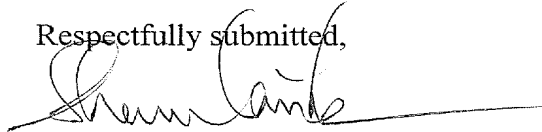
Applicants have added new Claim 32, which recites that the depth filter has a permeability of 110 or 220 L/m²/min. Support for this new claim is derived from the specification that lists the KS80 and K200 Seitz filters as embodiments of the present invention. The KS80 and K200 Seitz filters have a permeability of 110 and 220 L/m²/min, respectively.

CONCLUSION

For at least the reasons discussed above, Applicants respectfully submit that the application has been placed in condition for allowance, and Applicants respectfully request allowance of all the pending claims and passing this application to issue.

Any questions that the Examiner may have should be directed to the undersigned, who may be reached at (919) 854-1400.

Respectfully submitted,



Shawna Cannon Lemon
Registration No. 53,888

USPTO Customer No. 20792
Myers Bigel Sibley & Sajovec, P.A.
P. O. Box 37428, Raleigh, NC 27627
Telephone: (919) 854-1400
Facsimile: (919) 854-1401

CERTIFICATION OF TRANSMISSION

I hereby certify that this correspondence is being transmitted via the Office electronic filing system in accordance with § 1.6(e)(4) to the U.S. Patent and Trademark Office on February 13, 2007.



Susan E. Freedman

Date of Signature: February 13, 2007